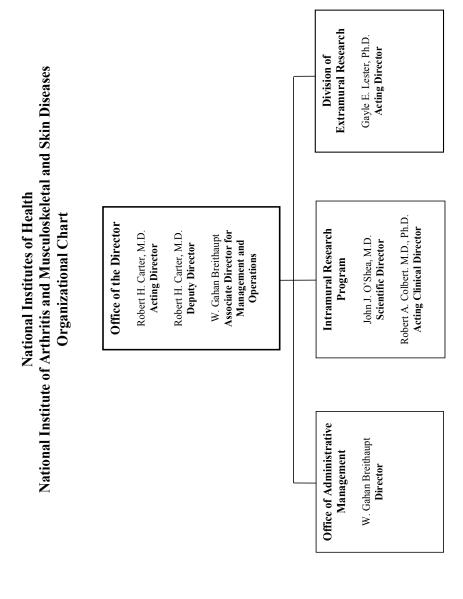
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## NATIONAL INSTITUTES OF HEALTH

# National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

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# NATIONAL INSTITUTES OF HEALTH

National Institute of Arthritis and Musculoskeletal and Skin Diseases For carrying out section 301 and title IV of the PHS Act with respect to arthritis and musculoskeletal and skin diseases, [\$605,065,000]\$520,829,000.

#### Amounts Available for Obligation<sup>1</sup>

(Dollars in Thousands)

Source of Funding	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Appropriation	\$586,661	\$605,065	\$520,829
Mandatory Appropriation: (non-add)			
Type 1 Diabetes	(0)	(0)	(0)
Other Mandatory financing	(0)	(0)	(0)
Rescission	0	0	0
Sequestration	0	0	0
Secretary's Transfer	-1,378	0	0
Subtotal, adjusted appropriation	\$585,283	\$605,065	\$520,829
OAR HIV/AIDS Transfers	0	0	0
HEAL Transfer from NINDS	0	0	0
Subtotal, adjusted budget authority	\$585,283	\$605,065	\$520,829
Unobligated balance, start of year	0	0	0
Unobligated balance, end of year	0	0	0
Subtotal, adjusted budget authority	\$585,283	\$605,065	\$520,829
Unobligated balance lapsing	-43	0	0
Total obligations	\$585,240	\$605,065	\$520,829

 $<sup>^{1}</sup>$  Excludes the following amounts (in thousands) for reimbursable activities carried out by this account:

FY 2018 - \$5,922 FY 2019 - \$6,064 FY 2020 - \$5,869

#### Budget Mechanism - Total<sup>1</sup>

(Dollars in Thousands)

MECHANISM	MECHANISM FY 2018 Final		MECHANISM FY 2018 Final FY 2019 Enacted			FY 2018 Final FY 2019 Enacted FY 2020 President's Budget		FY 2020 +/- FY 2019 Enacted		
	No.	Amount	No.	Amount	No.	Amount	No.	Amount		
January Davis atom										
Research Projects: Noncompeting	739	\$280,158	748	\$297,980	721	\$262,601	-27	-\$35,379		
Administrative Supplements	(39)	3,072	(30)	3,071	(24)	2,764	(-6)	-307		
Competing:	(39)	3,072	(30)	3,071	(24)	2,704	(-0)	-307		
Renewal	31	14,494	43	15,619	30	9,655	-13	-5,964		
New	235	81,475	187	67,510	132	42,673	-55	-24,837		
Supplements	0	01,475	0	07,510	1 1 1	218	1	218		
Subtotal, Competing	266	\$95,969	230	\$83,129	163	\$52.546	-67	-\$30.583		
Subtotal, RPGs	1,005	\$379,199	978	\$384,180	884	\$317,911	-94	-\$66,269		
SBIR/STTR	47	17,853	44	18,822	42	16,027	-24	-2,795		
Lesearch Project Grants	1,052	\$397,051	1,022	\$403,002	926	\$333,938	-96	-\$69,064		
escaren i roject Granis	1,032	\$397,031	1,022	\$405,002	920	\$333,736	-90	-302,00-		
lesearch Centers:										
Specialized/Comprehensive	39	\$40,872	44	\$46,985	44	\$42,287	0	-\$4,698		
Clinical Research	0	0	0	0	0	0	0	(		
Biotechnology	0	0	0	0	0	0	0	(		
Comparative Medicine	0	50	0	50	0	50	0	(		
Research Centers in Minority Institutions	0	0	0	0	0	0	0	(		
lesearch Centers	39	\$40,922	44	\$47,035	44	\$42,337	0	-\$4,698		
Other Research: Research Careers	141	\$20,750	146	\$21,643	146	\$21,643	0	\$(		
	141	\$20,750	146	\$21,043	146	\$21,043	0	\$(		
Cancer Education	0	0	0	0	0	0	0	(		
Cooperative Clinical Research	0	0	0	0	0	0	0	(		
Biomedical Research Support	0	250	0	٩	0	250	0	(		
Minority Biomedical Research Support	Ĭ		v	250	Ů	250	0	(		
Other Other Research	28 169	2,586 \$23,586	28 174	2,653 \$24,546	28 174	2,653	0			
Total Research Grants	1,260	\$23,586 \$461,559	1,240	\$24,546 \$474,583	1,144	\$24,546 \$400,821	-96	-\$73,762		
Total Research Grants	1,200	\$401,339	1,240	\$4/4,363	1,144	\$400,821	-90	-\$/3,/02		
tuth L Kirchstein Training Awards:	FTTPs		<u>FTTPs</u>		<u>FTTPs</u>		FTTPs			
Individual Awards	61	\$2,996	77	\$3,593	74	\$3,413	-3	-\$180		
Institutional Awards	220	11,924	232	13,175	222	12,516	-10	-659		
otal Research Training	281	\$14,920	309	\$16,768	296	\$15,929	-13	-\$839		
100 100		A		A15.		A15.				
desearch & Develop. Contracts	37	\$15,719	44	\$17,464	44	\$17,464	0	\$(		
(SBIR/STTR) (non-add)	(0)	(36)	(0)	(181)	(0)	(181)	(0)	(0)		
ntramural Research	124	60,755	139	62,821	139	56,539	0	-6,282		
les. Management & Support	97	32,330	99	33,429	99	30,076	0	-3,353		
Res. Management & Support (SBIR Admin) (non-add)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)		
								د .		
Construction		0		0		0		(		
buildings and Facilities Otal, NIAMS	221	\$585,283	238	\$605.065	238	\$520.829	0	-\$84,236		

<sup>&</sup>lt;sup>1</sup> All items in italics and brackets are non-add entries.

#### Major Changes in the Fiscal Year 2020 President's Budget Request

Major changes by budget mechanism and/or budget activity detail are briefly described below. Note that there may be overlap between budget mechanism and activity detail, and these highlights will not sum to the total change for the FY 2020 President's Budget request for NIAMS, which is \$520.8 million, a decrease of \$84.2 million from the FY 2019 Enacted level. The FY 2020 President's Budget reflects the Administration's fiscal policy goals for the Federal Government. Within that framework, NIAMS will pursue its highest research priorities through strategic investments and careful stewardship of appropriated funds.

#### Research Project Grants (RPGs) (-\$69.1 million; total \$333.9 million):

NIAMS will reduce funding for non-competing RPGs by 10.0 percent which is a \$29.2 million decrease from their full funding level. Competing RPGs are expected to decrease by 36 percent or 67 grants compared to the FY 2019 Enacted level of 230 awards, and the amount to support competing awards will be reduced by \$30.6 million from FY 2019. These reductions are distributed across all programmatic areas and basic, translational or clinical research. NIAMS continues to place a priority on support to early stage investigators.

#### Research Centers (-\$4.7 million; total \$42.3 million):

NIAMS will support a total of 44 research center awards. NIAMS will reduce funding for non-competing Centers by 10.0 percent which is a \$4.7 million decrease from the full funding level. The reductions are distributed across all programmatic areas.

#### Research Training (-\$0.8 million; total \$15.9 million):

NIAMS will support 296 pre-and postdoctoral trainees in full-time training positions, a 4.0 percent reduction in the number of trainees compared to the FY 2019 level. The Ruth L. Kirschstein NRSA budget reflects no stipend increase for the entry level trainees and fellows.

#### Summary of Changes

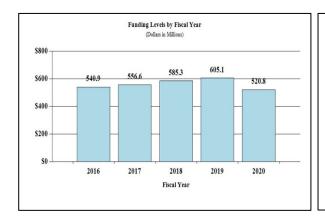
(Dollars in Thousands)

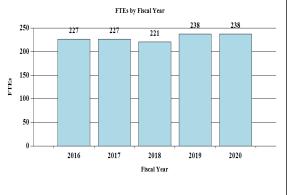
FY 2019 Enacted		\$605,065
FY 2020 President's Budget		\$520,829
Net change		-\$84,236
	FY 2020 President's Budget	Change from FY 2019 Enacted
CHANGES	FTEs Budget Authority	FTEs Budget Authority
A. Built-in:		
1. Intramural Research:		
Annualization of January 2019 pay increase & benefits	\$20,914	\$79
b. January FY 2020 pay increase & benefits	20,914	9
c. Paid days adjustment	20,914	80
d. Differences attributable to change in FTE	20,914	0
e. Payment for centrally furnished services	9,690	-1,077
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	25,935	692
Subtotal		-\$218
2. Research Management and Support:		
Annualization of January 2019 pay increase & benefits	\$16,871	\$61
b. January FY 2020 pay increase & benefits	16,871	61
c. Paid days adjustment	16,871	64
d. Differences attributable to change in FTE	16,871	0
e. Payment for centrally furnished services	3,505	-389
f. Cost of laboratory supplies, materials, other expenses, and non-recurring costs	9,700	232
Subtotal		\$29
Subtotal, Built-in		-\$189

	FY 2020 Preside	ent's Budget	Change from F	Y 2019 Enacted
CHANGES	No.	Amount	No.	Amount
B. Program:				
1. Research Project Grants:				
a. Noncompeting	721	\$265,365	-27	-\$35,686
b. Competing	163	52,546	-67	-30,583
c. SBIR/STTR	42	16,027	-2	-2,795
Subtotal, RPGs	926	\$333,938	-96	-\$69,064
2. Research Centers	44	\$42,337	0	-\$4,698
3. Other Research	174	24,546	0	0
4. Research Training	296	15,929	-13	-839
Research and development contracts	44	17,464	0	0
Subtotal, Extramural		\$434,214		-\$74,601
	FTEs		FTEs	
6. Intramural Research	139	\$56,539	0	-\$6,064
7. Research Management and Support	99	30,076	0	-3,382
8. Construction		0		0
9. Buildings and Facilities		0		0
Subtotal, Program	238	\$520,829	0	-\$84,047
Total changes				-\$84,236

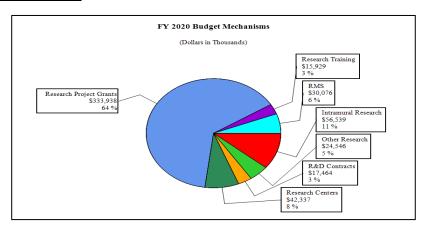
## Fiscal Year 2020 Budget Graphs

# History of Budget Authority and FTEs:

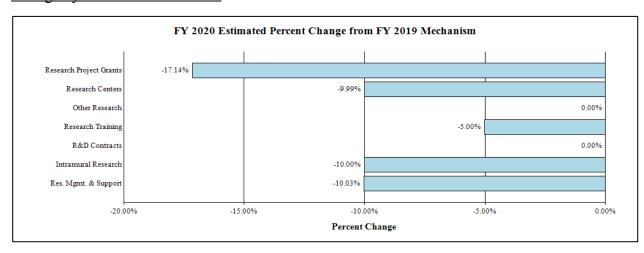




# <u>Distribution by Mechanism:</u>



# Change by Selected Mechanism:



# Budget Authority by Activity<sup>1</sup> (Dollars in Thousands)

	FY 2018 Final		FY 2019 Enacted		FY 2020 President's Budget		FY 2020 +/- FY2019	
Extramural Research	FTE	Amount	FTE	Amount	FTE	Amount	FTE	Amount
<u>Detail</u>								
Arthritis and Rheumatic Diseases		\$102,200		\$105,651		\$90,162		-\$15,489
Skin Biology and Diseases		98,019		101,329		86,474		-14,856
Muscle Biology and Diseases		71,885		74,313		63,418		-10,895
Musculoskeletal Biology and Diseases		133,523		138,027		117,786		-20,241
Bone Biology and Diseases		86,571		89,495		76,374		-13,120
Subtotal, Extramural		\$492,198		\$508,815		\$434,214		-\$74,601
Intramural Research	124	\$60,755	139	\$62,821	139	\$56,539	0	-\$6,282
Research Management & Support	97	\$32,330	99	\$33,429	99	\$30,076	0	-\$3,353
TOTAL	221	\$585,283	238	\$605,065	238	\$520,829	0	-\$84,236

<sup>&</sup>lt;sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and Musculoskeletal and Skin Diseases

# Authorizing Legislation

	PHS Act/	U.S. Code	2019 Amount	FY 2019 Enacted	2020 Amount	2020 Amount FY 2020 President's Budget
	Other Citation	Citation	Authorized		Authorized	
Research and Investigation	Section 301	42§241	Indefinite		Indefinite	
National Institute of Arthritis and Musculoskeletal and Skin Diseases	Section 401(a)	428281	Indefinite	\$605,065,000	Indefinite	\$520,829,000
		÷				
Total, Budget Authority				\$605,065,000		\$520,829,000

# **Appropriations History**

Fiscal Year	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
2011	\$555,715,000		\$554,846,000	\$539,082,000
Rescission				\$4,733,461
2012	\$547,891,000	\$547,891,000	\$528,332,000	\$536,801,000
Rescission				\$1,014,454
2013	\$535,610,000		\$537,233,000	\$535,786,446
Rescission				\$1,071,573
Sequestration				(\$26,892,795)
2014	\$540,993,000		\$537,398,000	\$520,053,000
Rescission				\$0
2015	\$520,189,000			\$521,665,000
Rescission				\$0
2016	\$533,232,000	\$528,137,000	\$544,274,000	\$542,141,000
Rescission				\$0
20171	\$541,662,000	\$555,181,000	\$564,131,000	\$557,851,000
Rescission				\$0
2018	\$417,898,000	\$566,515,000	\$576,178,000	\$586,661,000
Rescission				\$0
2019	\$545,494,000	\$593,663,000	\$605,383,000	\$605,065,000
Rescission				\$0
2020	\$520,829,000			

<sup>&</sup>lt;sup>1</sup> Budget Estimate to Congress includes mandatory financing.

#### **Justification of Budget Request**

#### National Institute of Arthritis and Musculoskeletal and Skin Diseases

Authorizing Legislation: Section 301 and title IV of the Public Health Service Act, as amended.

Budget Authority (BA):

			FY 2020	
	FY 2018	FY 2019	President's	FY 2020 +/-
	Actual	Enacted	Budget	FY 2019
BA	\$585,283,000	\$605,065,000	\$520,829,000	-\$84,236
FTE	221	238	238	0

TT 2020

Program funds are allocated as follows: Competitive Grants/Cooperative Agreements; Contracts; Direct Federal/Intramural and Other.

#### **Director's Overview**

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is the primary Federal agency responsible for supporting biomedical research on diseases of the bones, joints, muscles, and skin. The diseases and conditions within the NIAMS' mission areas touch the lives of virtually every American, impose significant financial burden, and reduce quality of life. For example, a new analysis of a 2015 self-reported national survey found about 91 million U.S. adults experience long-lasting pain, aching, or stiffness of their joints and may have some form of arthritis – 68 percent higher than the previously reported estimate of 54 million. Independent of 34 million and public health impacts of arthritis could be underestimated, including healthcare costs, loss of productivity, and disability.

Low back pain is the number one cause of years lived with disability across the world.<sup>3</sup> In addition, back pain is a major contributor to the use of opioids in the United States. NIAMS is leading the development of the NIH Back Pain Consortium Research Program (NIH BACPAC), a part of the NIH Helping to End Addiction Long-term program. The NIH BACPAC is envisioned as a highly collaborative, patient-centric translational research program that will dissect the components and mechanisms of chronic low back pain, and integrate data to identify, prioritize, and test treatments. The program's first awards, planned for FY 2019, are slated to include clinical research centers, technology development sites, data integration cores, and

<sup>&</sup>lt;sup>1</sup> Updated Estimates Suggest a Much Higher Prevalence of Arthritis in United States Adults Than Previous Ones. Jafarzadeh SR, Felson DT. *Arthritis Rheumatol*. 2018 Feb;70(2):185-192. doi: 10.1002/art.40355. PMID: 29178176. 
<sup>2</sup> Vital Signs: Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation — United States, 2013–2015. Barbour KE, Helmick CG, Boring M, Brady TJ. *MMWR Morb Mortal Wkly Rep* 2017;66:246–253. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm6609e1">http://dx.doi.org/10.15585/mmwr.mm6609e1</a>

<sup>&</sup>lt;sup>3</sup> Global, Regional, and National Incidence, Prevalence, and Years Lived with Disability for 328 Diseases and Injuries for 195 Countries, 1990-2016: A Systematic Analysis for the Global Burden of Disease Study 2016. GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. *Lancet*. 2017 Sep 16;390(10100):1211-1259. doi: 10.1016/S0140-6736(17)32154-2. PMID: 28919117

planning awards for future clinical trials. The research program will work to develop an integrated patient-based model of low back pain and facilitate the identification of treatments tailored to the individual patient. Ultimately, the program aims to reduce the use of opioids in the treatment of back pain.

As part of its ongoing scientific planning efforts, in FY 2019, NIAMS is revising the Institute's Long-Range Plan to a new Strategic Plan for FY 2020-2024. The new Plan will elaborate research opportunities related to the NIAMS mission and the many tissues and diseases of the bones, joints, muscle, skin, and immune system. NIAMS will maintain a strong commitment to the Institute's long-established principles to support the best investigator-initiated research, train the next generation of researchers, and foster innovation. For example, NIAMS recently renewed the Supplements to Advance Research (STAR) program, which is designed to support early-career investigators as they work to transition from a single project to a research program. In addition, the NIAMS Research Innovation for Scientific Knowledge (RISK) initiative encourages the pursuit of unusual observations, imaginative hypotheses, creative concepts, and ground-breaking paradigms that deviate significantly from current prevailing theories or practice. RISK is designed to promote scientific innovation by encouraging the submission of projects that are considered too risky, controversial, or unconventional for other programs.

#### **Building on Basic Research**

NIAMS invests in basic research that builds the foundation on which future translational research and new therapeutic interventions are made possible. Such investments, made years to decades in the past, formed the scientific premise and led to the development and recent approval of several treatments for both rare and common diseases. In April 2018, the Food and Drug Administration (FDA) approved the monoclonal antibody Crysvita (burosumab-twza) for people one year and older who have x-linked hypophosphatemia (XLH). XLH is a rare, inherited form of rickets that leads to impaired bone growth and development in children and adolescents, and problems with bone mineralization throughout a patient's life. The drug's development stems from an NIH grant funded in 1993 that led to the discovery of XLH's causative genetic defect and from other NIH-supported advances into the disease's underlying mechanism. Also in 2018, in the area of autoimmune diseases, Olumiant (baricitinib) became the second FDA-approved Janus kinase inhibitor for the treatment of moderate to severe rheumatoid arthritis. This class of drugs, called Jakinibs, is based on the landmark discovery of the JAK-STAT immune system signaling pathway in the early 1990s by NIH intramural researchers. Ongoing research is examining the safety and efficacy of this and other Jakinibs for a range of conditions – from certain cancers to autoimmune diseases such as psoriasis and lupus.

#### **Exploring the Next Frontiers in Biomedical Science**

An exciting area of research is the use of novel measures to support clinical decision making, as well as regulatory actions, to improve outcomes for patients. Since 2015, NIAMS has supported an effort to further the science of patient-reported outcomes (PROs) to improve pediatric health and well-being. Researchers are validating in children several PRO tools developed through the NIH Common Fund, called PROMIS® measures, to facilitate their application in pediatric research and clinical care settings. In addition, this consortium of researchers is working with

the FDA to qualify the PROs as clinical endpoints that capture the voices and experiences of children and their families living with a variety of chronic diseases and conditions. In another project, NIAMS is building on over 15 years of investments to identify and validate biomarkers for osteoarthritis. Through public-private partnerships among NIAMS and other NIH Institutes and Centers, the Foundation for the NIH (FNIH), and pharmaceutical companies, Osteoarthritis (OA) Initiative investigators established a public-domain resource to discover, evaluate, and validate biomarkers for osteoarthritis. In August 2018, the FNIH Biomarkers Consortium, NIAMS, and other public and private partners launched the *PROGRESS OA: Clinical Evaluation and Qualification of Osteoarthritis Biomarkers* project to build on earlier discoveries and seek regulatory qualification through the FDA of imaging and blood biomarkers that predict joint damage from OA over time. This qualification could enhance biomarker usage in drug development and pave the way for improved treatment, prevention, and diagnosis of this common joint disorder.

#### **Transformative Tools and Technologies**

The Accelerating Medicines Partnership for Rheumatoid Arthritis and Systemic Lupus Erythematosus (AMP RA/SLE), launched in September 2014, is a public-private partnership working to identify and validate promising biological targets for diagnostics and drug development. Over the last five years, the network of clinicians, translational researchers, and bioinformaticians have developed novel tools and techniques that have transformed the way researchers are approaching autoimmune disease. With phase 1 studies complete and phase 2 ongoing, data generated from cutting-edge technologies has been made publicly available for other researchers to interrogate. At the same time, the network has implemented numerous innovations in the conduct of research, including collaboration plans involving dispersed research institutions, standardization of sample processing protocols across multiple research sites, as well as patient recruitment strategies enhancing participation of underrepresented populations. These new models of research have allowed, for the first time, in-depth analysis of larger numbers of human tissues, from both patients and healthy volunteers, and will have a lasting impact on the field.

#### Overall Budget Policy:

The FY 2020 President's Budget request for NIAMS is \$520.8 million, a decrease of \$84.2 million or 13.9 percent compared with the FY 2019 Enacted level. These reductions are distributed across all programmatic areas and basic, epidemiology, or clinical research.

#### **Program Descriptions and Accomplishments**

#### **Bone Biology and Diseases**

This program supports projects ranging from fundamental research into the genetic and cellular mechanisms involved in the build-up and breakdown of bone to epidemiologic studies of lifestyle factors that can preserve bone health. The program leads collaborations with other NIH components to support large studies addressing osteoporosis and other age-related health issues. For example, the Study of Osteoporotic Fractures in women and the Osteoporotic Fractures in Men Study (MrOS), which examines osteoporosis and other age-related diseases in men, have

been underway since 1986 and 1999, respectively. In FY 2018, all anonymized data from the nearly 6,000 older men who participated in MrOS became available online to any researcher worldwide who registers at the study website. The increased availability of this NIH-funded resource will allow more investigators to build upon existing work into the determinants of bone loss, risk factors for falls and fractures, advanced imaging techniques for bone, strategies for screening for osteoporosis, and genetic influences on osteoporosis. In FY 2019, the program also oversaw a *Pathways to Prevention Workshop on the Appropriate Use of Drug Therapies for Osteoporotic Fracture Prevention* (see program portrait, below).

Recent data suggest that osteoporosis risk, fracture rates, and the cost of treatment are rising in the Hispanic population. These studies have focused mainly on Mexican Americans despite evidence that Hispanic subgroups have different rates of bone loss. Now, data from the Boston Puerto Rican Osteoporosis Study suggest that Puerto Rican and non-Hispanic white women have similar rates of osteoporosis, and that the middle-aged Puerto Rican men in this study are more likely to have osteoporosis than older Puerto Rican men. This finding is important because understanding osteoporosis and low bone mass in different populations will allow for better screening, diagnosis, and treatment that can lead to decreased overall costs and improved quality of life for those at risk or with disease.

Other research supported by this program focuses on therapies that are already used in clinical practice. Current HIV treatment guidelines call for all asymptomatic HIV-infected individuals to begin antiretroviral treatment at the time of diagnosis instead of waiting for their disease to progress before getting treatment. However, new research shows that people who begin antiretroviral treatment upon receiving their HIV diagnosis lose bone in the spine and hip more quickly than those who waited to begin antiretroviral treatment until after their immune system deteriorated. Assuming the decreased bone mineral density in this population is associated with increased fragility, the need for strategies to preserve the bones of people infected with HIV is expected to gain attention as more people live longer due to the unequivocal benefits of early antiretroviral treatment.

In addition to studying common conditions, such as low bone mass and osteoporosis mentioned above, this program supports a robust portfolio of rare disease research. In FY 2018, a group of researchers identified the cells responsible for excess bone growth, known as heterotopic ossification, which characterizes the rare bone disease fibrodysplasia ossificans progressiva (FOP). Characterizing the cells and molecules responsible for excessive bone formation may facilitate development of therapeutic approaches for FOP patients as well as wounded warriors, who often are affected by heterotopic ossification as a consequence of their injuries.

# Program Portrait: NIH Pathways to Prevention Workshop: Appropriate Use of Drug Therapies for Osteoporotic Fracture Prevention

FY 2019 level: \$56.6 million FY 2020 level: \$48.8 million Change: -\$7.8 million

Osteoporosis (a skeletal disorder that causes bones to become weak and fragile) and the fractures that it causes used to be considered a natural part of aging. Now we know that lifestyle changes can reduce a person's risk of developing the disease, and the more than 10 million people in the United States who have osteoporosis<sup>4</sup> have the option of taking drugs to prevent these debilitating and sometimes life-threatening fractures. Reducing osteoporosis prevalence and hip fracture incidence are among the major objectives of Healthy People 2020, the U.S. Department of Health and Human Services' national health promotion and disease prevention initiative.

Clinical guidelines by various medical organizations recommend bisphosphonates as a first line of treatment for most people who have osteoporosis. A few years of bisphosphonate use prevents fractures; however, reports of rare but serious side effects have raised questions regarding the drugs' safety for people who use the drugs for more than 3-5 years or who were at low risk of fracture when they began treatment. Public concern about rare side effects and other unanswered questions has coincided with a significant decrease in even the short-term use of osteoporosis drugs and a leveling off in what had been a promising decline in the incidence of osteoporotic fractures. <sup>5,6</sup>

In early FY 2019, NIAMS, the National Institute on Aging, and the NIH Office of Disease Prevention hosted a *Pathways to Prevention Workshop on the Appropriate Use of Drug Therapies for Osteoporotic Fracture Prevention* to assess the scientific evidence regarding osteoporosis drugs, such as bisphosphonates, and to better understand how the drugs should be used to prevent osteoporotic fractures. As part of the workshop process, a panel of scientists who are unaffiliated with the field of osteoporosis research are issuing an expert panel report that will be published in a leading medical journal. This report will lay the foundation for activities within and outside of the NIH and other federal agencies to develop research strategies and partnerships to improve public health that can be pursued in FY 2020 and beyond.

- <sup>4</sup> The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. Wright NC, Looker AC, Saag KG, Curtis JR, Delzell ES, Randall S, Dawson-Hughes B. *J Bone Miner Res.* 2014 Nov;29(11):2520-6. doi: 10.1002/jbmr.2269. PMID: 24771492
- <sup>5</sup> Trends in osteoporosis treatment with oral and intravenous bisphosphonates in the United States, 2002-2012. Wysowski DK, Greene P. *Bone*. 2013 Dec;57(2):423-8. doi: 10.1016/j.bone.2013.09.008. Epub 2013 Sep 21. PMID: 24063946
- <sup>6</sup> Hip fracture trends in the United States, 2002 to 2015. Michael Lewiecki E, Wright NC, Curtis JR, Siris E, Gagel RF, Saag KG, Singer AJ, Steven PM, Adler RA. *Osteoporos Int.* 2018 Mar;29(3):717-722. doi: 10.1007/s00198-017-4345-0. Epub 2017 Dec 27. PMID: 29282482

#### Budget Policy:

The FY 2020 budget estimate for this program is \$76.4 million, a decrease of \$13.1 million or 14.7 percent compared with the FY 2019 Enacted level. As highlighted in the program portrait above, program plans for FY 2020 include supporting research that will lead to a better understanding of how bone-building and bone-preserving drugs can better be used to prevent osteoporotic fractures.

#### Joint Biology and Diseases and Orthopaedics

This program focuses on understanding the fundamental biology of tissues that comprise the joints and on applying this knowledge to a variety of diseases and orthopaedic conditions. The portfolio covers research into causes and treatments for chronic back and neck pain, prevention

and repair strategies for joint injuries or joint diseases, and the development and application of imaging tools for monitoring osteoarthritis progression. Much of the Institute's regenerative medicine portfolio belongs in this program and plans for FY 2020 include encouraging investigators to participate in the NIH-wide Regenerative Medicine Innovation Project that is supported through the 21st Century Cures Act.

Examples of tissue engineering and regenerative medicine projects supported by this program include one from researchers who isolated stem cells from fat, grew them to make thin sheets, and tested whether the cells stimulate tendon healing in an animal model. Their results at two weeks post-surgery demonstrated that fat stem cells combined with a tendon growth-promoting factor speed up tendon repair and produce tissue that best resembles the normal tendon. Based on these promising results, the researchers are continuing to study long-term outcomes before testing this approach in people. Other groups are focusing on tissue engineering approaches to repair the knee meniscus. One new strategy to promote healing entails delivering two molecules associated with stem cell differentiation into the injured tissue via a single injection. The molecules were surrounded by polymers that dissolved at different rates: one molecule was released within five days and the other over five weeks. Single-injection approaches such as this are better positioned for clinical application than delivery systems that require multiple injections days or weeks apart. Future work includes evaluating the approach in large animal models and testing more complex tears.

Other work supported by this program has a more immediate impact on clinical research. When radiologists read magnetic resonance imaging or x-rays, they document this information in reports that ultimately become part of the patients' medical records. Because these reports lack a standard format, searching large numbers of them to identify people with similar imaging characteristics is cumbersome and slow. Researchers developed, evaluated, and validated a Natural Language Processing system to identify 26 low-back imaging findings. This new system capturing information from free text radiology reports can be applied to larger medical databases that investigators can search as part of low back pain studies and, ultimately, could be adapted to help coordinate the clinical care of patients with low back pain.

Another advance, this one with immediate application for the type of medical advice a person might receive, comes from the long-standing Osteoarthritis Initiative (OAI), a public-private partnership that NIH began in 2001. Running and other high-impact exercises have been thought to be detrimental to knee joints and consequentially make knee OA worse. New data from 1,200 of the OAI participants have shown that running is not associated with worsening of knee pain, nor with changes to the knee structure. Additionally, knee pain was more likely to improve in runners than in non-runners. These results suggest that running is safe and beneficial to runners with knee OA.

#### **Budget Policy:**

The FY 2020 budget estimate for this program is \$117.8 million a decrease of \$20.2 million or 14.7 percent compared with the FY 2019 Enacted level. Program plans for FY 2020 include working with the research community to explore scientific needs and opportunities related to the use of stem cells and other biologics when caring for patients with musculoskeletal injuries. In addition, the program will continue to promote the use of data and images collected as part of the

Osteoarthritis Initiative in studies of the epidemiology and natural history of osteoarthritis and its risk factors.

#### **Muscle Biology and Diseases**

This program's overarching objective is to explain muscle's role in health and, ultimately, to treat or prevent skeletal muscle diseases and disorders such as muscle ion channel diseases, inflammatory myopathies, disuse atrophy, skeletal muscle injury, and loss of muscle mass and strength associated with aging and diseases. The Institute's muscular dystrophy research portfolio, which includes the Senator Paul D. Wellstone Centers for Muscular Dystrophy Research, belongs to this program. NIAMS, the National Institute of Neurological Disorders and Stroke, NICHD, and the National Heart, Lung, and Blood Institute recently completed an evaluation of the Wellstone Centers program; this information will inform the development of the Centers that will be funded in FY 2020.

While skeletal muscle normally repairs and regenerates unless it is diseased or severely damaged, engineering functional skeletal muscles that are large enough to be therapeutically useful in people is challenging. A 2018 paper reported successful production of enough stem cells to generate 3-dimensional functional human skeletal muscles. Researchers demonstrated the ability to differentiate immature stem cells into cells that make muscle, identified conditions that allowed these cells to form 3-dimensional muscle bundles, and showed that these muscle bundles can generate force and respond to electrical and chemical stimulations. Furthermore, they implanted these muscle bundles into mice, where the bundles incorporated into the host mouse's muscle.

Other investigators are pursuing different approaches that also use stem cells to allow tissue to regenerate. One of the most significant challenges remaining for induced pluripotent stem cells (iPSC) transplantation for treating muscle diseases is the ability to get the cells, once the disease-causing defect has been corrected, to engraft into skeletal muscle and effectively replace the degenerated muscle with healthy tissue. In 2018, researchers described an iPSC-based method that led to an over 10-fold improvement compared with prior approaches in the engraftment of human muscle stem cells into a model of Duchenne muscular dystrophy. The approach provides step-by-step instructions and proof-of-concept for a stem cell-based therapy for muscle diseases, including the muscular dystrophies, which was previously not feasible.

Approximately a decade ago, researchers determined that inappropriate expression of a gene called *Dux4* in muscle cells causes cell death and leads to facioscapulohumeral muscular dystrophy. *Dux4* is expressed in sperm and egg cells and plays an essential role in the development of embryos shortly after fertilization, after which time it is silenced. In 2018, researchers identified two protein complexes that are responsible for silencing *Dux4* in normal cells and another protein family that contributes to *Dux4*'s upregulation and the spreading of its toxic gene products within the muscle cell. Modulation of any of these processes could represent an entire new class of therapeutics for this debilitating disease.

#### **Budget Policy:**

The FY 2020 budget estimate for this program is \$63.4 million, a decrease of \$10.9 million or 14.7 percent compared with the FY 2019 Enacted level. Program plans for FY 2020 include enabling research to advance understanding of human disease and promote the discovery of the causes, treatment and prevention of muscle diseases through the Institute's Musculoskeletal Biology and Medicine Resource-based Centers. In addition, NIAMS will continue participation in the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers program, as well as collaboration with other NIH components and federal agencies to advance research objectives in the 2015 Action Plan for the Muscular Dystrophies.

#### **Systemic Rheumatic and Autoimmune Diseases**

This program advances basic, translational, and clinical biomedical and biopsychosocial research to treat, cure, and prevent systemic rheumatic and autoimmune diseases. It supports the discovery and application of genetics, genomics, proteomics, immunology, and imaging insights to explain how the immune system interacts with various tissues in normal and pathological conditions. A major initiative of this program is the AMP RA/SLE referred to previously, which provides new knowledge about the biological mechanisms of these diseases. NIAMS currently is working to disseminate the wealth of data, methods, and other resources developed by the AMP to the broader scientific community. Sharing these resources helps to maximize the return on the investment in AMP by enabling many more researchers to mine the data for drug targets and scientific insights that could be used to develop new therapies for lupus and RA.

The NIAMS investment in RA research through initiatives like AMP is complemented by a sizable portfolio of investigator-initiated research projects. Several of these projects focus on the role of cells called fibroblast-like synoviocytes (FLS) in RA, which produce factors that cause joint damage, a defining feature of the disease. Scientists hope to develop anti-FLS therapies that could yield potentially safer and more effective treatments for RA when used in combination with existing therapies. NIAMS-funded investigators identified a specific subset of FLS in RA joints with a gene expression profile that is consistent with promoting bone destruction. Other researchers used advanced technologies to identify unique features of RA-FLS and reveal new cell signaling pathways active in the disease. Unexpectedly, this work showed that a signaling pathway associated with Huntington's disease, a fatal genetic brain disease, ranked top among RA pathways, even above many pathways that already had been implicated in RA. This startling overlap with Huntington's disease opens the possibility of new therapeutic targets and drugs for both conditions.

Patient-oriented lupus research within the program is paving the way for personalized and predictive treatments. For example, a growing body of evidence shows that tubulointerstitial damage (TID)—damage to the connective tissue between kidney structures—in lupus patients is a better predictor of progression to renal failure than other parameters that have been widely used to date. By analyzing medical records from a study of lupus patients, investigators showed that biomarkers commonly used to assess kidney disease in lupus do not correlate with TID. This finding highlights the need for new markers to identify TID and facilitate future development of therapies to prevent or reverse it. In addition, the study showed that hydroxychloroquine, a drug

commonly used to treat lupus, reduced the risk of tubulointerstitial inflammation, suggesting that the drug might be particularly beneficial in patients with TID.

Clinical efforts within the program are exploring new frontiers in patient-centered medical care. A pilot clinical trial of individuals at risk for RA tested whether providing them with personalized information through an easily accessible web-based tool would motivate behavior change. Participants who received information about their own genetic, clinical, and lifestyle risk factors were more likely to report increased motivation to change their behavior, e.g., to quit smoking to reduce their risk for RA. The results demonstrate the power of personalized medicine to engage patients in new and beneficial ways.

#### **Budget Policy**:

The FY 2020 budget estimate for this program is \$90.2 million, a decrease of \$15.5 million or 14.7 percent compared with the FY 2019 Enacted level. Program plans for FY 2020 include continued management of and support for the Accelerating Medicines Partnership in rheumatoid arthritis and lupus, including making additional data from the partnership widely available to the broader scientific community. Through continued leadership of the Lupus Federal Working Group, NIAMS will facilitate collaboration among the NIH Institutes and Centers, other Federal agencies, and voluntary and professional organizations with an interest in lupus.

#### **Skin Biology and Diseases**

This program supports basic, translational, and clinical research on the developmental and molecular biology of skin, the skin as an immune organ, and the genetics of skin diseases. A current initiative of this program seeks to accelerate basic and translational research in hidradenitis suppurativa, a chronic inflammatory skin disease that causes painful recurrent skin nodules. Because treatment options are limited for this condition, the initiative focuses on understanding the causes of the disease and applying new knowledge to improve outcomes for affected individuals.

Almost seven years ago, NIAMS issued an initiative to encourage translational and basic research on ways to control itch. Since that time, the Institute's portfolio and corresponding scientific knowledge in this area has grown appreciably. Importantly, this research has yielded potential new treatments to stop chronic itch, a symptom that can be debilitating for patients. For example, NIAMS-funded researchers unraveled the mechanism by which a molecule called the kappa opioid receptor (KOR) alleviates chronic itch. This work paves the way to design KOR-based therapies to halt chronic itching. Another study explored the role of the immune system in regulating chronic itch. It showed that the so-called JAK-STAT immune signaling pathway is active in chronic itch. Because this pathway is known to play a role in RA, the researchers tested a JAK inhibitor FDA-approved for use in RA in a small study of five chronic itch patients. The JAK inhibitor ameliorated chronic itch in these patients, who had not responded to other immunosuppressive therapies.

Better understanding of wound healing continues to be an important area within the program. With the advent of new technologies, researchers now have new tools to explore longstanding questions in this field. For example, while a great deal is known about how open wounds on the

skin's surface heal, relatively little is known about what happens when a wound is below the skin's surface. NIAMS-supported researchers developed a new imaging technique to track the movement and fate of living cells in mice. Using this method, they demonstrated that the skin has mechanisms to heal injuries that occur below its surface. This new technology will enable further research to understand wound healing in tissues deeper in the body.

#### Program Portrait: Understanding Co-Occurring Conditions in Psoriasis

FY 2019 level: \$8.6 million FY 2020 level: \$7.4 million Change: -\$1.2 million

Psoriasis, which causes scaly inflamed skin lesions, can also increase the risk for conditions such as cardiovascular disease, diabetes, and psoriatic arthritis. Recognizing the importance of addressing these co-occurring conditions, NIAMS supports research to predict which psoriasis patients are likely to experience associated health problems and determine how best to treat or manage them. In FY 2017, NIAMS held a meeting with researchers in dermatology and rheumatology to identify research needs related to psoriatic arthritis, a form of joint inflammation that can occur in people with psoriasis. NIAMS currently supports a center of translational research that is using bioinformatics techniques to analyze clinical and laboratory data from patients to identify drugs that could be repurposed to treat psoriasis and associated inflammatory conditions.

A number of NIAMS-funded studies have provided information that could improve treatment and management of co-occurring conditions. One such project, which examined the risk of type 2 diabetes in people with psoriasis, suggests a link between psoriasis severity and diabetes. The results underscore the importance of diabetes prevention in psoriasis, especially for those with severe disease. Another study showed that individuals with psoriasis, particularly those prescribed a systemic therapy, are at increased risk for developing liver disease, suggesting that patients on systemic therapy should minimize exposures, for example to certain medications, that may damage the liver. Other work tested whether the anti-inflammatory drug adalimumab mitigates the increased cardiovascular risk seen in patients with severe psoriasis. Although the drug was not effective at reducing cardiovascular risk factors, the results provide important new information for physicians as they decide the best course of treatment.

#### **Budget Policy:**

The FY 2020 budget estimate for this program is \$86.5 million, a decrease of \$14.9 million or 14.7 percent compared with the FY 2019 Enacted level. Program plans for FY 2020 include funding high impact projects through the Research Innovations for Scientific Knowledge (RISK) for Skin and Rheumatic Diseases program. In addition, this program plans continued support for the initiative to improve understanding of and treatments for hidradenitis suppurativa, a complex chronic inflammatory skin disease.

#### **Intramural Research Program (IRP)**

NIAMS' IRP conducts innovative basic, translational, and clinical research relevant to the NIAMS mission and trains investigators who are interested in related careers. Its basic and physician scientists study the genetics, etiology, pathogenesis, and treatment of rheumatic, autoimmune, inflammatory, bone, skin, and muscle diseases. For example, NIAMS intramural scientists are expanding the use of current technologies to inform personalized approaches for disease management. Large vessel vasculitis (LVV) is a group of inflammatory diseases

associated with inflammation of the aorta and large arteries, and clinical assessment of LVV does not always distinguish patients with active disease from those in remission. 18F-flurodeoxyglucose positron emission tomography (FDG-PET) is a well-established technique used to diagnose disease and monitor treatment response in cancer patients, but the technique's utility as a tool to assess inflammatory diseases was controversial. NIAMS IRP clinicians demonstrated that FDG-PET could be used in combination with clinical assessment to diagnose and monitor vascular inflammation in LVV patients, and could help predict the likelihood of future relapse in these patients, which may allow for earlier clinical intervention.

The Human Genome Project, completed in 2003, paved the way for researchers to build on that basic research and develop a more complete picture of how the genes are expressed. Currently, NIAMS intramural scientists are uncovering how genes are regulated during normal development and ways things can go awry in disease. One group has identified how certain immune cells rapidly change the structure of their genome to respond when they encounter foreign substances. Another group is exploring how DNA is organized by proteins within the cell to turn particular regions of the genome on or off. Their discoveries are beginning to elucidate how gene expression is controlled during cell differentiation, maintenance, or disease, and could help inform the development of drugs that impact gene expression, such as regenerative and precision medicine treatments.

#### Program Portrait: Elucidating novel mechanisms of genetic diseases

FY 2019 level: \$21.9 million FY 2020 level: \$18.9 million Change: -\$3.0 million

The NIAMS intramural translational and clinical research programs are harnessing the power of patients to identify the root cause of rare diseases and inform potential treatment approaches. One of the signature benefits of intramural research is the ability to assemble cohorts of patients, in collaboration with the NIH Clinical Center, who have rare diseases to fully characterize their conditions and potentially identify treatment options. For example, in a recent study, NIAMS intramural researchers, along with other NIH and academic collaborators, examined the genome of families and individuals affected by a newly identified immune syndrome. These patients experience both immunodeficiency – an impaired ability to respond to infections – and autoimmunity – an unwanted immune system attack on healthy tissues. The scientists revealed that one of the two copies of a particular gene, called BACH2, had been changed in the affected patients. This finding suggests that the amount of protein made from the remaining single normal copy of the BACH2 gene is insufficient to prevent disease, a scenario known as haploinsufficiency, and highlights the key role BACH2 plays in maintaining a healthy immune system.

In another study, researchers from NIAMS, NICHD, and other Institutes partnered with patients affected by a condition called melorheostosis. This rare disorder, with only about 400 known cases worldwide, causes excess bone formation that resembles dripping candle wax when viewed in x-rays. Researchers compared samples of healthy and affected bone from 15 participants with the disease to look for differences in the exome, the portion of the genome that codes for proteins. The analysis revealed that eight of the 15 participants had mutations in the *MAP2K1* gene, which produces the protein MEK1, in the affected bone only. MEK1 is already known to have a role in signaling pathways that promote cell growth and similar mutations have been observed in various forms of cancer. While the findings implicate MEK1 inhibition as a potential therapeutic strategy for melorheostosis treatment, the concept to harness this pathway in the future to treat weakening bones, as often occurs during aging, is also exciting.

#### **Budget Policy:**

The FY 2020 budget estimate for this program is \$56.5 million, a decrease of \$6.3 million or 10.0 percent compared to the FY 2019 Enacted level. Program plans for FY 2020 include continued support for basic and clinical investigations into the pathogenesis and treatment of rheumatic, skin, muscular and inflammatory diseases. Studies will combine the expertise of NIAMS investigators with the strengths of the NIH Clinical Center, and will include the study of rare diseases, innovative proof-of concept clinical trials, and longitudinal clinical studies. In addition, the IRP will continue to support the development of the next generation of physician-scientists and clinician-investigators through programs such as the NIAMS Scholars in Translational Research Program and adult and pediatric Rheumatology Training Programs for clinical fellows.

#### **Research Management and Support (RMS)**

The RMS budget supports the scientific, administrative management, and information technology activities associated with the NIAMS' day-to-day operations. In FY 2018, NIAMS managed 1,260 research grants and centers, as well as 37 research and development contracts and 281 individual and institutional full-time research training positions. NIAMS supported 574 clinical research studies, including 94 clinical trials.

### **Budget Policy:**

The FY 2020 budget estimate for this program is \$30.1 million, a decrease of \$3.4 million or 10.0 percent compared to the FY 2019 Enacted level. Program plans for FY 2020 include working with researchers, healthcare professionals, and health advocacy organizations to utilize and promote the Institute's new Strategic Plan. The plan will provide a broad outline of scientific opportunities and challenges, and will guide the Institute's priority-setting for FY 2020-2024. NIAMS will also continue to optimize and enhance the content, management, and functionality of the public website.

# **Budget Authority by Object Class<sup>1</sup>**

(Dollars in Thousands)

		FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Total co	mpensable workyears:			
	Full-time equivalent	238	238	0
	Full-time equivalent of overtime and holiday hours	0	0	0
	Average ES salary	\$190	\$190	\$1
	Average GM/GS grade	12.6	12.6	0.0
	Average GM/GS salary	\$113	\$114	\$0
	Average salary, grade established by act of July 1,	<b>#100</b>	#100	Φ.1
	1944 (42 U.S.C. 207)	\$190	\$190	\$1
	Average salary of ungraded positions	\$114	\$115	\$0
			FY 2020 President's	FY 2020
	OBJECT CLASSES	FY 2019 Enacted	Budget	+/-
			Duuget	FY 2019
	Personnel Compensation			
11.1	Full-Time Permanent	15,078	15,135	57
11.3	Other Than Full-Time Permanent	9,748	9,785	37
11.5	Other Personnel Compensation	860	863	3
11.7	Military Personnel	365	387	22
11.8	Special Personnel Services Payments	2,801	2,812	11
11.9	Subtotal Personnel Compensation	\$28,852	\$28,982	\$130
12.1	Civilian Personnel Benefits	8,509	8,730	221
12.2	Military Personnel Benefits	71	73	3
13.0	Benefits to Former Personnel	0	-	0
	Subtotal Pay Costs	\$37,432	\$37,785	\$354
21.0	Travel & Transportation of Persons	674	476	-198
22.0	Transportation of Things	93	61	-31
23.1	Rental Payments to GSA	0	0	0
23.2	Rental Payments to Others	0	0	0
23.3	Communications, Utilities & Misc. Charges	404	271	-133
24.0	Printing & Reproduction	0	-	0
25.1	Consulting Services	1,582		-597
25.2	Other Services	5,949	4,371	-1,578
25.3	Purchase of goods and services from government	56,246	47,511	-8,736
25.4	accounts	-		
25.4	Operation & Maintenance of Facilities	25	15	-10
25.5	R&D Contracts	4,003	857	-3,147
25.6	Medical Care	5,931	4,520	-1,411
25.7	Operation & Maintenance of Equipment	1,456	1,148	-308
25.8	Subsistence & Support of Persons	14		-3
25.0	Subtotal Other Contractual Services	\$75,207		- <b>\$15,789</b> -1,025
26.0 31.0	Supplies & Materials Equipment	4,344 3,875	· ·	-1,025 -1,126
32.0	Land and Structures	3,8/3		-1,120
33.0	Investments & Loans	0		0
41.0	Grants, Subsidies & Contributions	483,037	*	44 200
41.0	Insurance Claims & Indemnities	483,037	416,749	-66,288
43.0	Interest & Dividends	0	0	0
44.0	Refunds	0	0	
77.0	Subtotal Non-Pay Costs	\$567,633	\$483,044	-\$84,590
	Total Budget Authority by Object Class	\$605,065		-\$84,236

<sup>&</sup>lt;sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.

#### **Salaries and Expenses**

(Dollars in Thousands)

OBJECT CLASSES	FY 2019 Enacted	FY 2020 President's Budget	FY 2020 +/- FY 2019
Personnel Compensation			
Full-Time Permanent (11.1)	\$15,078	\$15,135	\$57
Other Than Full-Time Permanent (11.3)	9,748	9,785	37
Other Personnel Compensation (11.5)	860	863	3
Military Personnel (11.7)	365	387	22
Special Personnel Services Payments (11.8)	2,801	2,812	11
Subtotal Personnel Compensation (11.9)	\$28,852	\$28,982	\$130
Civilian Personnel Benefits (12.1)	\$8,509	\$8,730	\$221
Military Personnel Benefits (12.2)	71	73	3
Benefits to Former Personnel (13.0)	0	0	0
Subtotal Pay Costs	\$37,432	\$37,785	\$354
Travel & Transportation of Persons (21.0)	\$674	\$476	-\$198
Transportation of Things (22.0)	93	61	-31
Rental Payments to Others (23.2)	0	0	0
Communications, Utilities & Misc. Charges (23.3)	404	271	-133
Printing & Reproduction (24.0)	0	0	0
Other Contractual Services:			
Consultant Services (25.1)	1,582	985	-597
Other Services (25.2)	5,949	4,371	-1,578
Purchases from government accounts (25.3)	40,806	32,227	-8,578
Operation & Maintenance of Facilities (25.4)	25	15	-10
Operation & Maintenance of Equipment (25.7)	1,456	1,148	-308
Subsistence & Support of Persons (25.8)	14	11	-3
Subtotal Other Contractual Services	\$49,832	\$38,758	-\$11,073
Supplies & Materials (26.0)	\$4,344	\$3,319	-\$1,025
Subtotal Non-Pay Costs	\$55,346	\$42,885	-\$12,461
Total Administrative Costs	\$92,778	\$80,671	-\$12,107

## **Detail of Full-Time Equivalent Employment (FTE)**

	]	FY 2018 Final		F	Y 2019 Enacte	d	FY 2020	President's	Budget
OFFICE/DIVISION	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Intramural Research Program									
Direct:	123	-	123	138	-	138	138	-	138
Reimbursable:	1	-	1	1	-	1	1	-	1
Total:	124	-	124	139	-	139	139	-	139
Office of Extramural Activities									
Direct:	45	1	46	46	1	47	46	1	47
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	45	1	46	46	1	47	46	1	47
Office of the Director									
Direct:	51	-	51	52	-	52	52	-	52
Reimbursable:	-	-	-	-	-	-	-	-	-
Total:	51	-	51	52	-	52	52	-	52
Total	220	1	221	237	1	238	237	1	238
Includes FTEs whose payroll obligations are supported by the	NIH Common	Fund.							
FTEs supported by funds from Cooperative Research and	0	0	0	0	0	0	0	0	0
Development Agreements.	U	U	U	Ü	U	U	U	U	U
FISCAL YEAR				Ave	erage GS Gra	de			
2016					12.4				
2017					12.5				
2018					12.6				
2019					12.6				
2020					12.6				

#### Detail of Positions1

GRADE	FY 2018 Final	FY 2019 Enacted	FY 2020 President's Budget
Total, ES Positions	1	1	1
Total, ES Salary	189,600	189,600	190,320
GM/GS-15	24	24	24
GM/GS-14	26	26	26
GM/GS-13	53	60	60
GS-12	22	31	31
GS-11	8	8	8
GS-10	0	0	0
GS-9	6	6	6
GS-8	4	4	4
GS-7	4	4	4
GS-6	1	1	1
GS-5	2	2	2
GS-4	0	0	0
GS-3	0	0	0
GS-2	0	0	0
GS-1	0	0	0
Subtotal	150	166	166
Grades established by Act of July 1, 1944 (42 U.S.C. 207)	0	0	0
Assistant Surgeon General	0	0	0
Director Grade	1	1	1
Senior Grade	0	0	0
Full Grade	1	1	1
Senior Assistant Grade	1	1	1
Assistant Grade	0	0	0
Subtotal	3	3	3
Ungraded	87	87	87
Total permanent positions	150	166	166
Total positions, end of year	237	253	253
Total full-time equivalent (FTE) employment, end of year	221	238	238
Average ES salary	189,600	189,600	190,320
Average GM/GS grade	12.6	12.6	12.6
Average GM/GS salary	114,216	113,221	113,651

<sup>&</sup>lt;sup>1</sup> Includes FTEs whose payroll obligations are supported by the NIH Common Fund.